



75 North Fairway Drive
Vernon Hills, Illinois 60061
BD.com

URGENT FIELD SAFETY NOTICE

Affected product:

**MANOMETER TRAY
JAMSHIDI NEEDLE BIOPSY
ILLINOIS (TJ) NEEDLE ASPIRATION
JAMSHIDI (TJ) NEEDLE BONE MARROW
THORACENTESIS/PARACENTESIS KIT**

FSCA reference number: ISRC-2017-0001

Type of Action: Product Removal

March 9, 2017

Dear Business Partner:

CareFusion a subsidiary of BD is voluntarily performing a Medical Device Recall to remove affected devices subject to the below described potential risk.

DETAILS ON THE AFFECTED DEVICES:

Manometer Tray, Jamshidi Needle Biopsy, Illinois (TJ) Needle Aspiration, Jamshidi (TJ) Needle Bone Marrow, Thoracentesis/Paracentesis Kit

This recall applies to the following:

Attachment "A" - Affected Product – Lot Code List

Attachment "B" - Graphics on where to locate the Product Code; Lot Code

DESCRIPTION OF THE PROBLEM:

CareFusion a subsidiary of BD has identified a potential risk associated with the packaging integrity - open seal of the affected products. If this failure is not recognized prior to a procedure it has the potential to result in an inflammatory / infectious response locally and/or systemically.

Six (6) customer complaints have been received to date in the time frame of 01-NOV-2014 to 31-DEC-2016 with the issue of sterile packaging integrity. In all 6 reports the failure was recognized on visual inspection prior to patient use. No cases have been reported of patient(s) experiencing a serious injury or illness.

ACTION TO BE TAKEN BY THE CUSTOMER / USER:

- Check your inventory for the affected devices and place them in quarantine
- Complete the Customer Response Form certifying that all affected product in your inventory has been placed in quarantine and mail/email a copy of the response form to:

CareFusion France 309 S.A.S
8 bis rue de la Renaissance
44110 Châteaubriant
France
Beatrice.Lambert@bd.com
+33 2 28 50 40 70

- Please ***promptly return*** the enclosed Customer Response Form to expedite the correction process and acknowledge receipt of this notification.
- **Transmission of this Field Safety Notice**

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

ACTIONS TO BE TAKEN BY CareFusion *a subsidiary of BD*:

At receipt of your customer response form, Carefusion will inform you about further action to be taken of your quarantined products and a credit will be applied to your account for the affected product after certification and documentation of the required actions.

We appreciate your ***prompt return*** of the enclosed Customer Response Form to expedite the correction process and acknowledge receipt of this Notification.

This Field Safety Notice has been notified to the appropriate Regulatory Agency.



75 North Fairway Drive
Vernon Hills, Illinois 60061
BD.com

We recognize the inconvenience this issue may cause your facility and thank you for your support in this important matter.

Sincerely,

[Redacted signature block]

Enclosure(s): Customer Response Form
 Affected Product Code List (Attachment "A")
 Graphics on where to locate the Product Code; Lot Code
 (Attachment "B")

URGENT FIELD SAFETY NOTICE

CUSTOMER RESPONSE FORM**Acknowledgment and Verification Form**

Product Reference: 4330; SN1015X; SN1016X; SN1017X; SN7016X; TIN3015;
TIN3018; TJC3513; TJC4008; TJC4011; TJC6008; TJC6011; TJM3513;
TJM4008; TJM4011; TJM6008; TJM6011; TPK1001

Refer to attachment "A" for Product - Lot Code list

FSCA #: **ISRC-2017-0001**

| | |
|--|--|
| Name of Hospital / Facility | |
| Distributor | |
| Hospital / Facility Distributor | |
| Address | |
| Name | |
| Telephone number | |
| Email address | |
| Signature | |
| Date | |

- ☐ I have read and understand the contents of this Field Safety Notice and confirm that our inventory has been checked, and we no longer have the affected product in our inventory
- ☐ I have read and understood the contents of this Field Safety Notice and confirm that our medical equipment inventory has been checked, and we have the following affected product in our inventory



75 North Fairway Drive
Vernon Hills, Illinois 60061
BD.com

| Model Number | Lot Number | QTY |
|--------------|------------|-----|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

Note: If more space is needed for the above table please attach a separate document.

☐

Wholesaler/Distributor only: I have identified and notified all customers that purchased any affected product. Check below which method of notification was used (**Include date and method**):

Date of Notification:_____

Mail__; **E-mail**__; **Fax**__ ; **Phone**__



75 North Fairway Drive
Vernon Hills, Illinois 60061
BD.com

The following person shall be contacted to coordinate the action (please complete if different than above)

| | |
|-------------------------|--|
| Name | |
| Telephone Number | |
| Email | |

Please return a copy of the Customer Response Form to:

CareFusion France 309 S.A.S
8 bis rue de la Renaissance
44110 Châteaubriant
France
Beatrice.Lambert@bd.com
+33 2 28 50 40 70

Once the form has been returned to CFN we will be contacting you regarding the disposition on any affected products.

URGENT Field Safety Notice
AFFECTED PRODUCT / LOT CODES

ATTACHMENT "A"

| Product Code | Lot Code | Product Description |
|---------------------|-----------------|--|
| 4330 | 0000837810 | MANOMETER TRAY STERILE 10/BX |
| 4330 | 0000840335 | MANOMETER TRAY STERILE 10/BX |
| 4330 | 0000842213 | MANOMETER TRAY STERILE 10/BX |
| 4330 | 0000848531 | MANOMETER TRAY STERILE 10/BX |
| 4330 | 0000851181 | MANOMETER TRAY STERILE 10/BX |
| 4330 | 0000853962 | MANOMETER TRAY STERILE 10/BX |
| SN1015X | 0000840334 | JAMSHIDI NEEDLE BIOPSY 15G X 100MM DISP |
| SN1016X | 0000848028 | JAMSHIDI NEEDLE BIOPSY 16G X 100MM DISP |
| SN1017X | 0000848018 | JAMSHIDI NEEDLE BIOPSY 17G X 100MM DISP |
| SN7016X | 0000848017 | JAMSHIDI NEEDLE BIOPSY 16G X 70MM DISP |
| TIN3015 | 0000836578 | ILLINOIS (TJ) NEEDLE ASPIRATION 15GA |



75 North Fairway Drive
Vernon Hills, Illinois 60061
BD.com

| Product Code | Lot Code | Product Description |
|--------------|------------|---|
| TIN3015 | 0000838953 | ILLINOIS (TJ) NEEDLE ASPIRATION 15GA |
| TIN3015 | 0000841213 | ILLINOIS (TJ) NEEDLE ASPIRATION 15GA |
| TIN3015 | 0000841215 | ILLINOIS (TJ) NEEDLE ASPIRATION 15GA |
| TIN3015 | 0000842719 | ILLINOIS (TJ) NEEDLE ASPIRATION 15GA |
| TIN3015 | 0000842721 | ILLINOIS (TJ) NEEDLE ASPIRATION 15GA |
| TIN3015 | 0000845423 | ILLINOIS (TJ) NEEDLE ASPIRATION 15GA |
| TIN3015 | 0000848061 | ILLINOIS (TJ) NEEDLE ASPIRATION 15GA |
| TIN3015 | 0000849715 | ILLINOIS (TJ) NEEDLE ASPIRATION 15GA |
| TIN3015 | 0000850938 | ILLINOIS (TJ) NEEDLE ASPIRATION 15GA |
| TIN3015 | 0000852076 | ILLINOIS (TJ) NEEDLE ASPIRATION 15GA |
| TIN3015 | 0000854859 | ILLINOIS (TJ) NEEDLE ASPIRATION 15GA |
| TIN3018 | 0000836574 | ILLINOIS (TJ) NEEDLE ASPIRATION 18GA |
| TIN3018 | 0000841212 | ILLINOIS (TJ) NEEDLE ASPIRATION 18GA |
| TIN3018 | 0000852078 | ILLINOIS (TJ) NEEDLE ASPIRATION 18GA |

| Product Code | Lot Code | Product Description |
|--------------|------------|--|
| TJC3513 | 0000848831 | JAMSHIDI (TJ) NEEDLE BONE MARROW 13GX3.5 |
| TJC3513 | 0000851431 | JAMSHIDI (TJ) NEEDLE BONE MARROW 13GX3.5 |
| TJC3513 | 0000854856 | JAMSHIDI (TJ) NEEDLE BONE MARROW 13GX3.5 |
| TJC4008 | 0000841227 | JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X4 |
| TJC4008 | 0000846706 | JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X4 |
| TJC4008 | 0000848560 | JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X4 |
| TJC4008 | 0000849684 | JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X4 |
| TJC4008 | 0000853455 | JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X4 |
| TJC4011 | 0000840667 | JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4 |
| TJC4011 | 0000841228 | JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4 |
| TJC4011 | 0000845874 | JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4 |
| TJC4011 | 0000849717 | JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4 |
| TJC4011 | 0000850937 | JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4 |
| TJC4011 | 0000852121 | JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4 |

| Product Code | Lot Code | Product Description |
|--------------|------------|--|
| TJC6008 | 0000841216 | JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X6 |
| TJC6008 | 0000848569 | JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X6 |
| TJC6008 | 0000851432 | JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X6 |
| TJC6008 | 0000852122 | JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X6 |
| TJC6008 | 0000853458 | JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X6 |
| TJC6011 | 0000841124 | JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X6 |
| TJC6011 | 0000848571 | JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X6 |
| TJC6011 | 0000853975 | JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X6 |
| TJM3513 | 0000836582 | JAMSHIDI (TJ) NEEDLE BM 13G X3.5 ASP MAC |
| TJM3513 | 0000838949 | JAMSHIDI (TJ) NEEDLE BM 13G X3.5 ASP MAC |
| TJM3513 | 0000843968 | JAMSHIDI (TJ) NEEDLE BM 13G X3.5 ASP MAC |
| TJM3513 | 0000849685 | JAMSHIDI (TJ) NEEDLE BM 13G X3.5 ASP MAC |
| TJM3513 | 0000852933 | JAMSHIDI (TJ) NEEDLE BM 13G X3.5 ASP MAC |
| TJM4008 | 0000841349 | JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC |

| Product Code | Lot Code | Product Description |
|--------------|------------|---|
| TJM4008 | 0000841348 | JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC |
| TJM4008 | 0000843961 | JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC |
| TJM4008 | 0000849132 | JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC |
| TJM4008 | 0000852123 | JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC |
| TJM4008 | 0000853877 | JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC |
| TJM4011 | 0000836575 | JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC |
| TJM4011 | 0000838950 | JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC |
| TJM4011 | 0000840195 | JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC |
| TJM4011 | 0000843075 | JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC |
| TJM4011 | 0000843076 | JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC |
| TJM4011 | 0000846708 | JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC |
| TJM4011 | 0000852932 | JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC |
| TJM4011 | 0000853878 | JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC |
| TJM4011 | 0000854861 | JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC |

| Product Code | Lot Code | Product Description |
|--------------|------------|--|
| TJM4011 | 0000854983 | JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC |
| TJM6008 | 0000842725 | JAMSHIDI (TJ) NEEDLE BM 8G X 6 ASP MAC |
| TJM6008 | 0000853971 | JAMSHIDI (TJ) NEEDLE BM 8G X 6 ASP MAC |
| TJM6011 | 0000843077 | JAMSHIDI (TJ) NEEDLE BM 11G X6 ASP MAC |
| TJM6011 | 0000849713 | JAMSHIDI (TJ) NEEDLE BM 11G X6 ASP MAC |
| TJM6011 | 0000854659 | JAMSHIDI (TJ) NEEDLE BM 11G X6 ASP MAC |
| TPK1001 | 0000837811 | THORACENTESIS/PARACENTESIS KIT 10/CS |
| TPK1001 | 0000842215 | THORACENTESIS/PARACENTESIS KIT 10/CS |
| TPK1001 | 0000840336 | THORACENTESIS/PARACENTESIS KIT 10/CS |
| TPK1001 | 0000851185 | THORACENTESIS/PARACENTESIS KIT 10/CS |



75 North Fairway Drive
Vernon Hills, Illinois 60061
BD.com

**URGENT: Medical Device Recall
PACKAGING INTEGRITY – OPEN SEAL**

**Graphics on where to locate the Product Code / Lot
Code**

ATTACHMENT "B"

Product code: 4330

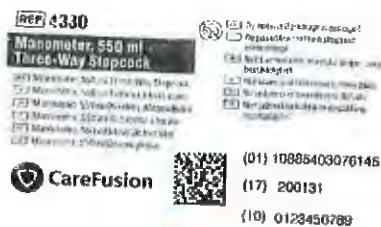
See graphics below on where to locate part number and lot number.

Lot Code Case

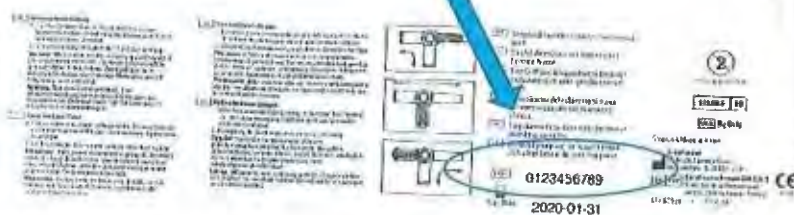


Lot number on Case Label

Lot Code Unit



Lot number on Pouch Label



Product code: TPK1001

See graphics below on where to locate part number and lot number.

Lot Code Case

REF TPK1001 X 10

Thora-Para 8 Fr Catheter Drainage Kit

Thoracocentesis/Paracentesis Catheter Drainage Kit
 Kit de drainage pour cathéter pour thoracocentèse/paracentèse
 Katheterdrainagekit für die Thoracocentese/Paracentese
 Kit de drenaggio con catetere per toracocentesi/paracentesi
 Kit de drenaje de catéter de toracocentesis/paracentesis
 Drainageet Thoracocentesis/Paracentesis-kateter
 Toracocentesi/paracentesiskateteriäsetä für kateter
 Pleuralipisturi/Paracentesiskat.
 Pleura-järvelistopunktiön- ja dreneraussatja
 Orenasaset for thoracocentesis-/paracentesiskat.
 Katnapajenset for thoracocentesis-/paracentesiskat.
 胸管 / 胸腔穿刺用カテーテルドレインキット

STERILE EO

エチレンオキサイドガス滅菌済
 Sterilized with natural rubber latex

CareFusion
 75 North Fairway Drive
 Vernon Hills, IL 60061 USA
 CareFusion France 309 S.A.S.
 8 bis rue de la Renaissance
 44110 Châteaubriant - France
 CE 0123

Sponsored by
 CareFusion Australia 316 Pty. Ltd.
 CareFusion New Zealand 313 Ltd.
 371-60612 Rev 4

Scalpel Made in India
 Extension Set Made in China
 S-In-1 Adapter Made in
 Dominican Republic

LOT 1234567890

製造番号
2020-04-30
 Exp. Date
 使用期限

CareFusion

1007

20

101 200430 (10) 1234567890

101 50085403074129

Lot Code Unit

REF TPK1001

Thora-Para 8 Fr Catheter Drainage Kit

Thoracocentesis/Paracentesis Catheter Drainage Kit
 Kit de drainage pour cathéter pour thoracocentèse/paracentèse
 Katheterdrainagekit für die Thoracocentese/Paracentese
 Kit de drenaggio con catetere per toracocentesi/paracentesi
 Kit de drenaje de catéter de toracocentesis/paracentesis
 Kit de cateter de drenagem de toracocentesi/paracentese
 Drainageet Thoracocentesis/Paracentesis-kateter
 Toracocentesi/paracentesiskateteriäsetä für kateter

da Pleurapunktiun/Paracentesaset
e Pleura- ja vatsantopunktiön- ja dreneraussatja
no Drenasjeset for thoracocentesis-/paracentesiskateter
el Katnapajenset for thoracocentesis-/paracentesiskateter
ja 胸管 / 胸腔穿刺用カテーテルドレインキット

STERILE EO

エチレンオキサイドガス滅菌済
 For Single Use Only
 再使用しないで下さい
 Do not use if package is damaged
 Consult instructions for use
 Not made with natural rubber latex

USA Rx Only

Scalpel Made in India
 Extension Set Made in China
 S-In-1 Adapter Made in Dominican Republic

LOT

製造番号

Exp. Date
 使用期限

CareFusion

75 North Fairway Drive
 Vernon Hills, IL 60061 USA
 CareFusion France 309 S.A.S.
 8 bis rue de la Renaissance
 44110 Châteaubriant - France
 CE 0123

Sponsored by
 CareFusion Australia 316 Pty. Ltd.
 CareFusion New Zealand 313 Ltd.
 371-60612 Rev 4

Barcode Here

Lot number on Pouch Label

Product code: TJ or TIN

See graphics below on where to locate part number and lot number.

Lot Code Case



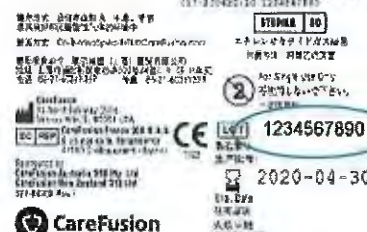
- [illegible]



1071 3055567363213



Lot number on Case Label

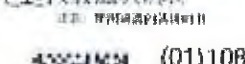
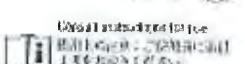
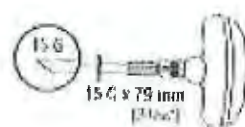
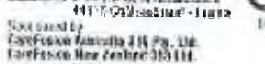
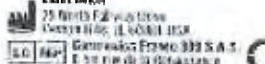
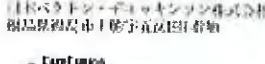
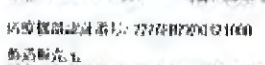
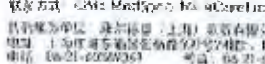
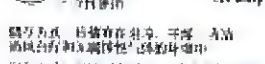
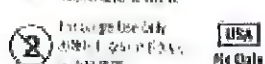
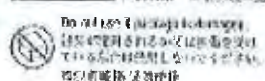


1234567890

2020-04-30

Lot Code Unit

- [illegible]



Lot number on Pouch Label

Product code: SN ____ X

See graphics below on where to locate part number and lot number.

Lot Code Case



Lot number on Case Label

Lot Code Unit



Lot number on Pouch Label